

**REMARKS**

The Abstract stands objected to for use of legal phrases, specifically, the term “consisting of.”

Claims 1-8 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for use of the terms “abruptly,” “warm,” “rapid” and “hot.”

Claims 1-6 and 8 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,952,370 to Cummings, *et al.* (“Cummings”).

Claims 1-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,512,951 to Koubek (“Koubek”).

Claim 7 stands rejected under 35 U.S.C. §103(a) as unpatentable over Cummings in view of U.S. Patent No. 5,525,295 to Pflug, *et al.* (“Pflug”).

Finally, double-patenting rejections have been entered against the pending claims in view of the claims in co-pending applications Ser. Nos. 09/941,925, 10/363,546 and 10/759,071.

**1. The Abstract Has Been Amended to Address the Objection.**

The Applicants have amended the Abstract to eliminate the word “consisting,” and to address minor spelling issues. Withdrawal of the pending specification objection is respectfully requested.

**2. Withdrawal of the § 112 Rejections Is Requested.**

The Applicants respectfully request withdrawal of the pending § 112 rejections, on the grounds that one of ordinary skill in the art, reading the claims in the context of the description of the invention in the specification, would readily understand the scope of the claims.

As noted in the MPEP, “[t]he fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. MPEP § 1504.04II. The MPEP specifically quotes the *In re Moore* case as teaching that “[T]he definiteness of the language employed must be analyzed – not in a vacuum, but always in the light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *Id.* The Applicants respectfully submit that the present claims use these terms in exactly this manner.

First, one of ordinary skill in the art would be presumed to be aware of the well-known conventional sterilization processes, in which an object to be sterilized is exposed by relatively slow flooding of a chamber with a sterilization agent. With this basic knowledge, those of ordinary skill are taught by the present specification about sterilization processes in which an over-saturated sterilization vapor is formed and then “*abruptly* deposited in a time spanning *a few tenths of a second to a maximum of a few seconds*” to form a condensate layer on the object. Specification ¶ [0003]. The Specification then describes at length the application of such a process in the present invention. Thus, one of ordinary skill in the art would readily understand that the present invention’s “abrupt” creation of an over-saturated mixture by rapid expansion and cooling is “flash”-type, or a nearly instantaneous process, as compared to drawn-out prior art sterilizing exposure processes (such as dipping or slow flowing of gas over an object. Thus, the term is “abrupt” is sufficiently definite, as it would

immediately be recognized by one of ordinary skill as referring to the essentially immediate change in mixture state to a liquid, rather than the prior art's non-instant-phase-change exposure processes.

Consistent with the guidance set forth in the MPEP, the Applicants respectfully submit that because the claims provide one of ordinary skill a sufficiently definite definition of the processes to which the present invention is directed, no further refinement of the term "abruptly," such as a numerical limitation, is required.

Similarly, the specification makes clear that the terms "warm" and "hot" refer to temperatures above the temperature of the target objects and/or the sterilization chamber (depending on context), as the specification contains extensive discussions as to the beneficial effect that even small increases in temperature can have in improving desorption of the sterilizing film from the sterilized surfaces. *See, e.g.*, Specification ¶¶ [0004]-[0011]. Thus, one of ordinary skill would readily understand that "warm" and "hot" are relative terms that have a definite reference point – *i.e.*, higher temperature than the objects and/or chamber surfaces. Accordingly, the Applicants respectfully submit these terms are sufficiently definite for the purposes of § 112.

As to the remaining term, "rapid-acting," the Applicants have amended claims 8 to remove this term. The Applicants note that this amendment is made without any intent to alter the scope of claim 8, as in the context of the present invention, a hot air current applied in the recited manner is inherently a "rapid-acting" air current.

**3. The Claims Are Patentable Over Cummings.**

The Applicants respectfully traverse the rejections based on Cummings, on the grounds that this reference does not disclose or suggest the features of the present invention for which it is cited.

The Present Invention: The present invention provides an apparatus and method in which objects are sterilized in a sterilizing chamber in a manner which enhances the evacuation of residual sterilizing fluids following the performance of an abrupt deposition and removal of a sterilizing vapor.

In the present invention, an aqueous hydrogen peroxide solution is abruptly expanded in a sterilization chamber which has wall surfaces which neither adsorb condensing vapor nor conduct any significant heat away from the chamber. The resulting over-saturation condition in the vapor causes nearly instantaneous formation of a condensate film on the surfaces of the objects to be sterilized. The formation of the hydrogen peroxide film is so rapid, the resulting release of the heat of evaporation (enthalpy) heats the hydrogen peroxide before it can be transferred to the surface of the object, an effect which greatly increases the disassociation of the hydrogen peroxide and the resultant effectiveness of the sterilization. Following condensation, the bulk of the residual condensate is rapidly evacuated from the object's surfaces and the chamber structures by vacuum. As noted at, for example, Specification ¶ [0026], while most of the film is readily removed in this way, a small fraction remains attracted to the surfaces by dipole bonds which require additional energy to break free. The Applicants determined that the completeness of the sterilization film removal could be

significantly enhanced by pre-warming the surfaces to increase their molecular energy level (molecular vibrations), without detrimental effect on the effectiveness of the enthalpy-heating of the sterilizing film in disassociating the hydrogen peroxide.

The Cummings Reference: In contrast to the present invention, Cummings discloses essentially continuous hydrogen peroxide injection flow into a chamber whose surfaces must be maintained at specific temperatures in order to support sterilization.

Cummings teaches a relatively long sterilization process, which consequently introduces a number of complications to the process. In Cummings: (i) in order for a condensation film to form on the surfaces to be sterilized, the surfaces must be initially at a temperature below that of the incoming mixture of water vapor and hydrogen peroxide (*i.e.*, gradual condensation by absorption of heat from the vapor by the cold surface); (ii) additional hydrogen peroxide must be continuously injected into the sterilization chamber in order to maintain a sufficient concentration of hydrogen peroxide on the cold surface as the hydrogen peroxide both disassociates and evaporates in the presence of a water-removing vacuum; (iii) a water-removing vacuum must be carefully maintained *between* the evaporation point of water and the evaporation point of hydrogen peroxide; and (iv) the cold surface must be continuously cooled to ensure its temperature does not rise. Cummings at 2:41-64 ("The vapor phase hydrogen peroxide is continued to be introduced into the chamber until the surfaces are sterile while preserving the temperature ranges

of both the first [10°C] and second [20°C] portions of the surfaces.”); 3:47-54 (vacuum established to preferentially extract water); 3:55-60 (“injections of vapor phase hydrogen peroxide continue, thereby establishing a flow through the system”); 5:57-7:7 (full process description).

In addition to complicated steps to maintain the required environmental conditions, Cummings also disadvantageously requires considerable time to achieve the desired sterilization. *See, e.g.*, Cummings at 6:14-16 (initial vapor introduction “for approximately one minute”); 6:44-48 (subsequent additional hydrogen peroxide injections over 4 to 32 minutes).

Thus, Cummings discloses a cumbersome, time-consuming sterilization process requiring constant, careful parameter monitoring and maintenance. This reference, by relying on relatively slow condensation from a *sub-saturated* vapor, neither anticipates, nor provides any suggestion in the direction of, the present invention’s sterilization by rapid generation of an over-saturated vapor which immediately condenses on surfaces, without the need to carefully monitor or maintain surface temperatures or other environmental parameters such as the level of vacuum applied during drying.

Cummings thus neither discloses or suggests the present invention, including the present invention’s vapor mix which is “rapidly expanded ... such that the vapor mix cools to below the hydrogen peroxide dew point, the said vapor mix being deposited in the form of a condensate layer abruptly on the surfaces of the objects to be sterilized ... wherein the condensate layer is heated up by the released evaporation enthalpy, and wherein the condensate layer is

subsequently sucked out immediately thereafter by further evacuation of the sterilization chamber, wherein at least one of the surfaces of the objects to be sterilized and the sterilization chamber are pre-heated to a pre-determined temperature.” The present invention therefore is patentable over Cummings under §§ 102(b) and 103(a). The Applicants respectfully request the pending §§ 102(b) and 103(a) rejections be reconsidered and withdrawn.

**4. The Claims Are Patentable Over Koubek.**

The Applicants respectfully traverse the rejection based on Koubek, on the grounds that this reference does not disclose or suggest the features of the present invention for which it is cited.

The Koubek reference is cited as teaching the application of steam and hydrogen peroxide to the surface of articles to be sterilized, and the preheating of the system to prevent premature condensation before contacting all the surfaces. October 21, 2004 Office Action at 3-4.

The Applicants respectfully submit that Koubek discloses nothing more than the exposure of an object in an open tray to a hydrogen peroxide vapor. Koubek at 2:40-56; Fig. 1. There is no teaching or suggestion of the present invention’s approach use of an abrupt formation of an over-saturated hydrogen peroxide vapor which immediately condenses on surfaces such that the heat released in the phase change heats the hydrogen peroxide to cause its rapid disassociation and resulting surface sterilization. Rather, the Koubek process is a slow “dip” process, with each “dip” being caused by continued condensation and application of a fresh pure liquid sterilant to evacuated surfaces. As disclosed in

Koubek, this is not a rapid process, taking from minutes to hours to complete. Koubek at 4:64-65. As to preheating, Koubel teaches the preheating of surfaces to *prevent* premature formation of a condensate on the objects, and thus teaches away from the present invention's approach of forming the condensate film so quickly that the heat released from condensation does not have sufficient time to transfer to the object before the hydrogen peroxide is disassociated.

Because Koubek does not disclose or suggest the present invention's abrupt phase-changing approach to sterilization, claims 1-8 are patentable over this references under § 102(b). Reconsideration and withdrawal of the pending § 102(b) reaction is respectfully requested.

**5. The Double Patenting Rejections Should Be Withdrawn.**

The Applicants respectfully traverse the pending provisional double patenting rejections of the claims over claims 1-20 of co-pending Application Ser. No. 09/941,925, claims 1-16 of co-pending Application Ser. No. 10/363,546 and claims 1-18 of co-pending Application Ser. No. 10/759,071, on the grounds that these claims are patentably distinct from the present invention.

Ser. No. 10/363,546: The present claims are directed to a process and apparatus in which an over-saturated vapor mixture is abruptly formed in a sterilization chamber, which then immediately condenses on the surfaces of the objects to be sterilized.

The claims in co-pending Application Ser. No. 10/363,546 on the other hand, are directed to use of an under-saturated (i.e., superheated) vapor mixture, which is established in a chamber. This superheated mixture passes through a

liquid-proof anti-bacterial barrier cover into a package, then condenses on a component. The sterilizing liquid film is then again put in a vapor state by evaporation to permit it to pass back out of the liquid-proof barrier cover and be withdrawn from the chamber.

The Applicants respectfully submit that this is not the “same inventive concept” as in the present invention’s over-saturation-based sterilization approach, *i.e.*, no claim in the present application could be literally infringed while literally infringing a claim in the corresponding application. Accordingly, the pending provisional double-patenting rejection should be withdrawn.

Ser. No. 10/759,071: The claims of this Application are directed to the use of a low-heat conducting, non-adsorptive material for the structural members (*e.g.*, walls) of the sterilization chamber, in order to minimize condensation on the chamber walls depleting the vapor volume so that the target objects in the chamber are completely sterilized. The Applicants respectfully submit that a *prima facie* showing of obviousness of either the present claims over the ‘071 claims, or the ‘071 claims over the present claims, sufficient to support the pending provisional obviousness-type double-patenting rejection, has not been made.

The present application is entirely silent as to the material of its sterilization chamber wall, and contains nothing which would suggest to one of ordinary skill that any particular wall material would be advantageous. While it is asserted in the October 21, 2004 Office Action that use of the claimed chamber materials is “intrinsic” to the present invention’s over-saturation condensation

process (Office Action at 6), there is nothing in the present application which suggests, nor any explanation in the Office Action as to how, the claimed process “intrinsically” requires the use of such chamber materials. Rather, there is nothing in the record which suggests that the presently claimed process cannot be practiced in a metal-walled sterilization chamber. Moreover, there is nothing in the cited art teaching or suggesting the use of low-heat conducting, non-adsorptive materials to avoid excessive hydrogen peroxide-depleting vapor condensation away from a target surface in a over-saturation condensation process. Considered from the ‘071 Application, this Application teaches the use of a novel sterilization process which relies on the use of low-heat conducting, non-adsorptive chamber materials in order to ensure the sterilization process can be completed without condensation on the walls resulting in inadequate hydrogen peroxide concentrations at the surfaces of the objects to be sterilized. There is nothing in the ‘071 Application which teaches or suggests the use of the present claims’ preheating of surfaces to enhance evacuation of the residual dipole-bonded molecules after the sterilization has been completed.

In the absence of any teaching or suggestion which renders either the present claims or the claims of the ‘071 Application obvious in view of one another, the threshold requirement for an obvious-type provisional double-patenting rejection have not been met, and this rejection should be withdrawn.

Ser. No. 09/941,925: The claims of the ‘925 Application are directed to a non-obvious variant of the present invention. As noted above, the present invention relies on essentially adiabatic expansion of the hydrogen peroxide

vapor to generate an over-saturated mixture, and causes a target surface to be sterilized by sudden heating of the condensed mixture (*i.e.*, the hydrogen peroxide is heated before the heat dissipates into the target, causing oxygen atoms to disassociate and become available to destroy bacteria).

Because the '925 claims are directed to a process which does not rely on an external heat source to cause the hydrogen peroxide, there is no teaching or suggestion in the present application for the preheating of the target objects and/or the chamber as recited in the present claims. Conversely, the present Application teaches a sterilization process which requires preheating to ensure the sterilization process is completely effective by removal of residual dipole-bonded sterilant *after* the sterilization which occurs when the hydrogen peroxide condenses on the object surfaces.

As with the '071 Application, in the absence of any teaching or suggestion which renders either the present claims or the claims of the '925 Application obvious in view of one another, this rejection should be withdrawn.

### CONCLUSION

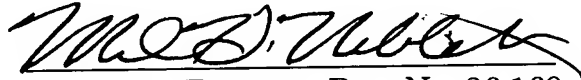
In view of the foregoing amendments, the Applicants respectfully submit that claims 1-8 are now in allowable form. Early and favorable consideration and issuance of a Notice of Allowance for these claims is respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029082.53121US).

February 22, 2005

Respectfully submitted,



Donald D. Evenson, Reg. No. 26,160

Mark H. Neblett, Reg. No. 42,028

CROWELL & MORING, LLP  
P.O. Box 14300  
Washington, DC 20044-4300  
Telephone No.: (202) 624-2500  
Facsimile No.: (202) 628-8844